

IFW

Docket No.: 0152-0725PUS1  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Noboru FUKUDA et al.

Application No.: 10/570,159 ✓

Confirmation No.: N/A

Filed: March 1, 2006

Art Unit: N/A

For: TGF- $\beta$  GENE EXPRESSION INHIBITOR

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT**  
**(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL**  
**REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE 1.114**  
**RCE APPLICATION)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

☒ a. Copies of cited U.S. patents and patent application publications are not included.  
Copies of foreign patent documents and non-patent literature are included.

☐ b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

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☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☐ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☒ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows: **English abstracts are attached for JP 3045706, WO 03/000683, and JP 2001-136974. Watanabe et al., Gendaiiryo, Vol. 35, No. 2, 2003, pp.86-91, with Partial English translation, Makino N. et al., Gendaiiryo, Vol. 35, No. 2, 2003, pp. 111-116, with Partial English translation, and Fukuda, Gene Therapy for Arterial Proliferative Diseases and Progressive Renal Diseases by Nucleic Acid Medicines, Vol. 62, No. 7, pp.329-336, 2003.**

☐ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☒ d. OTHER - The following additional information is provided for the Examiner's consideration. **WO 02/08468 was cited in a previous Information Disclosure Statement dated March 1, 2006.**

IV. FEES (check one box)

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☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☒ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. *(This section is not to be used with RCE's.)*

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☐ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

☐ f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.  
or

☐ See the statement below. No fee is required.

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V. STATEMENT UNDER 37 C.F.R. § 1.97(e)(check only one box)

The undersigned hereby states that:

- ☐ a. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or
- ☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- ☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

- ☐ The required fee is listed on the attached Fee Transmittal.
- ☒ No fee is required.

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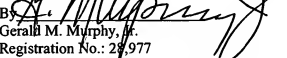
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If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated:

Respectfully submitted,

  
By Gerald M. Murphy, Jr.  
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Attachment(s):

☒ PTO-SB08  
☒ Documents

J. M. K.



PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				Application Number	10/570,159
				Filing Date	March 1, 2006
				First Named Inventor	Noboru FUKUDA
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	0152-0725PUS1

U.S. PATENT DOCUMENTS					
Examiner Initials <sup>1</sup>	Cite No.	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS					
Examiner Initials <sup>1</sup>	Cite No.	Foreign Patent Document Country Code <sup>3</sup> -Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	BA	JP-3045706-B1	03-17-2000		
	BB	JP-2001-136974-A	05-22-2001		
	BC	WO-03/000683-A1	01-03-2003		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>1</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>2</sup> See Kinds Codes of Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>3</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>4</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>		
	CA	Piek et al., FASEB J., Vol. 13, No. 15, pp.2105-2124, 1999			
	CB	Battaller R. et al., Gastroenterology, Vol. 118, No. 6, 2000, pp. 1149-1156			
	CC	Watanabe et al., Gendai Iryo, Vol. 35, No. 2, 2003, pp.86-91, with English translation			
	CD	Yamamoto F. et al., Kidney International, Vol. 49, No. 2, 1996, pp.461-469			
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	CF	Ono et al., Circulation, 1998, Vol. 98, pp. 149-156			
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	CJ	Mori et al., Journal of Cellular Physiology, Vol. 181, pp.153-159, 1999			
	CI	Reilly J. et al., Clinical Haematology, Vol. 11, No. 4, 1998, pp.751-767			
	CK	Martyn M C et al., British Journal of Haematology, 1991, Vol. 77, pp.80-86, 1991			
	CL	Rameshwar P. et al., American Journal of Hematology, Vol. 59, No. 2, 1998, pp.133-142			
	CM	Rameshwar P. et al., The Journal of Immunology, Vol. 165, No. 4, pp.2271-2277, 2000			
	CN	Shigeki et al., FASEB Journal, Vol. 16, pp. 1967-1969, 2002			
	CO	Trauger et al., Nature, Vol. 382, No. 6591, pp.559-561, 1996			
	CP	White et al., Chemistry & Biology, Vol. 4, No. 8, pp. 569-578, 1997			
	CQ	Dervan, Bioorganic & Medicine Chemistry, Vol. 9, pp.2215-2235, 2001			
	CR	White et al., Nature, Vol. 391, pp. 468-471, 1998			
	CS	Gottesfeld et al., Nature, Vol. 387, pp. 202-205, 1997			
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	CU	Lee et al., Proc. Natl. Acad. Sci. USA, Vol. 93, pp.2570-2575, 1996			
	CV	Dickinson et al., Biochemistry, Vol. 38, pp.10801-10807, 1999			
	CW	Mapp et al., Proc. Natl. Acad. Sci. USA, Vol. 97, pp.3930-3935, 2000			
	CX	Fukuda, Gene Therapy for Arterial Proliferative Diseases and Progressive Renal Diseases by Nucleic Acid Medicines, Vol. 62, No. 7, pp.329-336, 2003			

Examiner Signature	Date Considered
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Birch, Stewart, Kolasch &amp; Birch, LLP

GMM/JMK/ta

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /TH/



PTO/SB/08a/b (07-05)  
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Substitute for form 1449A/B/PTO		<b>Complete if Known</b>	
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		Filing Date	March 1, 2006
		First Named Inventor	Noboru FUKUDA
		Art Unit	N/A
		Examiner Name	Not Yet Assigned
Sheet	2	of	2
		Attorney Docket Number	0152-0725PUS1

CY	Janssen et al., Molecular Cell, Vol. 6, pp. 1013-1024, 2000	
CZ	Janssen et al., Molecular Cell, Vol. 6, pp. 999-1011, 2000	
CA1	Hu et al., Journal of Hypertension, Vol. 19, No. 2, pp. 203-212, 2001	
CB1	Teng et al., Cardiovascular Research, Vol. 48, pp. 138-147, 2000	
CC1	Lee et al., Cell, Vol. 67, pp. 1241-1250, 1991	
CD1	Starr et al., Cell, Vol. 67, pp. 1231-1240, 1991	
CE1	Courey et al., Cell, Vol. 55, pp. 887-898, 1988	
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CI1	Kim et al., The Journal of Biological Chemistry, Vol. 264, No. 1, pp. 402-408, 1989	
CJ1	Kadonaga et al., Cell, Vol. 51, pp. 1079-1090, 1987	
CK1	Kim et al., The Journal of Biological Chemistry, Vol. 264, No. 12, pp. 7041-7045, 1989	
CL1	Kim et al., The Journal of Biological Chemistry, Vol. 264, No. 32, pp. 19373-19378, 1989	
CM1	Kim et al., Molecular and Cellular Biology, pp. 1492-1497, Vol. 10, No. 4, 1990	
CN1	Birchenaill-Roberts et al., Molecular and Cellular Biology, Vol. 10, No. 9, pp. 4978-4983, 1990	
CO1	Aso et al., The EMBO Journal, Vol. 13, No. 2, pp. 435-445, 1994	
CP1	Mack et al., Nature, Vol. 363, pp. 281-283, 1993	
CQ1	Merino et al., Nature, Vol. 365, pp. 227-232, 1993	
CR1	Berger et al., Molecular Cell, Vol. 8, pp. 263-268, 2001	
CS1	McKeown, Annu. Rev. Cell Biol., Vol. 8, pp. 133-155, 1992	
CT1	Decker et al., Trends Biochem Sci., Vol. 19, pp. 336-340, 1994	
CJ1	Kozak, Annu. Rev. Cell Biol., Vol. 8, pp. 197-225, 1992	
CV1	Gottesfeld et al., Journal of Molecular Biology, Vol. 321, pp. 249-263, 2002	
CW1	Gottesfeld et al., Journal of Molecular Biology, Vol. 309, pp. 615-629, 2001	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*Applicant's unique citation designation number (optional). \*Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Thomas Heard/	Date Considered	08/24/2009
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Birch, Stewart, Kolasch & Birch, LLP

GMM/JMK/ka

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /TH/